



ISO/CASCO CLARIFICATION REQUEST FORM

Date of submission: 12 April 2018

1. Requesting ISO Member or A liaison member: IFIA
2. Contact person: Samuel Hill
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5. Please specify the ISO/CASCO document by name and number (ISO/IEC 17XXX) and clause number: ISO/IEC 17025:2017 8.5
6. Clarification request, please formulate the request clearly and where possible in a format that enables a YES or NO answer: ISO/IEC 17025 Section 1 (Scope) states that ISO/IEC 17025 “specifies general requirements for the competence, impartiality and consistent operation of laboratories.” The standard itself thus establishes that all requirements therein pertain to the competence, impartiality and consistent operation of laboratories. ISO/IEC 17025:2017 clause 8.5 is titled “Actions to address risks and opportunities”. In the context of the scope the risks and opportunities addressed by requirements in 8.5 are those related to the competence, impartiality and consistent operation of laboratories. Other risks and opportunities (e.g., financial, market share, contractual) are outside the scope of the 8.5 requirements if they have no impact on the competence, impartiality or consistent operation of the laboratory. Is this correct?
7. Consensus position of the maintenance group (This section is only to be completed by the maintenance group members) The clarifications requested appear to be hypothetical as insufficient information has been supplied related to these specific problems associated with the implementation of the standard. Contractual, financial, organizational and market share risks and opportunities may impact the competence, impartiality and consistent operation of laboratories. The standard enables a holistic approach to the evaluation of risks and opportunities and it is the laboratory’s decision which risks and opportunities should be considered. Furthermore, the Working Group’s intention of limiting the impact of “Risk” only relates to the methodology applied. “Risk Management” and the implementation of a formal risk management system (e.g, ISO 31000) is not a requirement.

Send the filled form to casco@iso.org